Docket No. 2629-4005US4

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Lorincz, A. Group Art Unit: TBA

CONTINUATION of
Serial No. : 09/210,168 Examiner: TBA

Filed : December 11, 1998

For : **ASSESSMENTS OF HUMAN PAPILLOMA VIRUS-RELATED DISEASE**

PRELIMINARY AMENDMENT

Commissioner for Patents
Box Patent Application
Washington, D.C. 20231

Dear Sir:

Prior to examination and calculation of the filing fee, please amend the application as follows.

IN THE CLAIMS

Please cancel claims 1-7 and add the following new claims.

8. A method of diagnosing risk of HPV-induced neoplasia by detecting HPV-induced cell transformation in a patient infected with HPV comprising the steps of:

- quantifying levels of at least two HPV mRNAs from a sample collected from said patient, wherein said mRNAs comprise a first mRNA selected from the group consisting of E6 mRNA and E7 mRNA and a second mRNA selected from the group consisting of E2 mRNA, L1 mRNA, and L2 mRNA; and

- determining a ratio of E6 and/or E7 mRNA to L1 and/or L2 and/or E2 mRNA , wherein any ratio of greater than 2 is indicative of HPV-induced cell transformation and risk of neoplasia.

9. A method of diagnosing the onset of HPV-induced neoplasia in a patient infected with HPV comprising the steps of:

- quantifying a group 1 and a group 2 and/or a group 3 HPV mRNA from a sample collected from said patient;

- determining a ratio of group 1 mRNA level to group 2 and/or group 3 mRNA level wherein any ratio of greater than 2 is indicative of HPV-induced neoplastic onset.

10. A method of diagnosing stage of HPV-induced disease in a patient infected with HPV comprising the steps of:

- quantifying levels of HPV mRNA from a sample collected from said patient;

- determining the level of E6 and/or E7 mRNA and the level of E2 and/or L1 and/or L2 mRNA; and

- determining a ratio of E6 and/or E7 mRNA level to L1 and/or L2 and/or E2 mRNA level wherein any ratio of greater than 2 is indicative of early stage HPV-induced disease, thereby diagnosing the stage of HPV-induced disease in a patient infected with HPV.

11. A method of diagnosing HPV-induced cancer in a patient infected with HPV comprising the steps of:

- quantifying levels of at least two HPV mRNAs from a sample collected from said patient, wherein said mRNAs comprise a first mRNA selected from the group consisting of E6 mRNA and E7 mRNA and a second mRNA selected from the group consisting of

E2 mRNA, L1 mRNA, and L2 mRNA; and

- determining a ratio of E6 and/or E7 mRNA to L1 and/or L2 and/or E2 mRNA, wherein any ratio of greater than 4 is indicative of HPV-induced cancer.

12. A method of diagnosing the risk or onset of HPV-induced cancer in a patient infected with HPV comprising the steps of:

- quantifying a group 1 and a group 2 and/or a group 3 HPV mRNA from a sample collected from said patient; and

- determining a ratio of group 1 mRNA level to group 2 and/or group 3 mRNA level wherein any ratio of greater than 4 is indicative of high risk or onset of HPV-induced cancer.

REMARKS

Applicants respectfully request favorable consideration of the present application and claims. The newly added claims are supported by the original specification and do not introduce any new matter. Early and favorable action by the Examiner is earnestly solicited.

No additional fee is believed to be necessary.

The Commissioner is hereby authorized to charge any additional fees which may be required for this amendment, or credit any overpayment to Deposit Account No. 13-4500, Order No. 2629-4005US4.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition and for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. 13-4500, Order No. 2629-4005US4. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,

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Date: October 4, 2001

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